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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/508,746	03/19/2005	Meong-Gun Song	53850-10100	6244

23337 7590 12/09/2009

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EXAMINER	
MILLER, CHERYL L	

ART UNIT	PAPER NUMBER
3738	

NOTIFICATION DATE	DELIVERY MODE
12/09/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

USPTO_Mail@hro.com

Office Action Summary	Application No.	Applicant(s)	
	10/508,746	SONG, MEONG-GUN	
	Examiner	Art Unit	
	CHERYL MILLER	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 September 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,5,6,13,15,16,22 and 23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,5,6,13,15,16,22, and 23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 3, 2009 has been entered.

Response to Arguments

Applicant's arguments with respect to claims 1, 4-7, 10, 12, 13, 15-18, and 22-25 have been considered but are moot in view of the new ground(s) of rejection.

The applicant has argued with respect to the Lansac (US 2005/0065597 A1) rejection, that the present invention predates the Lansac priority date. The examiner disagrees. The Lansac publication claims priority to provisional application 60/552,199 filed on March 12, 2004 which is earlier than applicants priority date. The 597' publication appears to be fully supported by the 199' provisional application.

The applicant has argued that Chevillon (US 6,511,506 B1) does not disclose an outer discontinuous device and an inner discontinuous device (two separate discontinuous devices). The examiner disagrees as this is not what is claimed. The applicant has claimed a single discontinuous device (not specifying if it is on an inner or outer or both parts of the device). Chevillon discloses an inner and outer device (150 and 29; 150 disclosed to be made similar to 29), both shown in fig.1 to be discontinuous. The continuous device may be considered element 31 (formed as a loop with no free ends). The applicant has argued further that Chevillon's

device is not capable of placement in an aortic valve lumen. The examiner disagrees. Chevillon's device is used in the vasculature and thus would fit in other vessels including the aortic lumen as well. It has a size/shape/configuration that would allow placement in such a location. Although it may cover a native valve, a replacement valve may be inserted inside Chevillon's device. Further, whether the native valve would function properly or be harmed is not the issue at hand, instead the issue is if Chevillon's device has a size/shape that would physically fit in such a location, which is seems it would. The applicant has also argued that Chevillon does not disclose devices made of synthetic fibers. The examiner disagrees. Chevillon discloses use of such materials in making up the devices (col.2, lines 31-34; col.6, lines 21-23).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 5, 6, and 22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In claim 1, lines 14-16, a continuous STJ stabilizing device is required to stabilize both the inside and outside of the STJ. This is considered new matter as "a continuous sinotubular junction stabilizing device" is seemingly one device (at least termed so in the specification-either the inner or outer ring) thus it is unclear how it may be provided on the

inside and outside of the STJ at the same time. Also, if applicant is considering the continuous STJ stabilizing device to be two components, it is unclear how it may be termed "continuous" if the inner and outer parts are discrete (discontinuity between them). Claims 5, 6, and 22 depend upon claim 1 and inherit all problems with the claim. Applicant may want to consider instead claiming, "a sinotubular junction stabilizing device comprising a continuous inner ring adapted to stabilize the inside of the sinotubular junction and a continuous outer ring adapted to stabilize the outside of the sinotubular junction". Similar problems exist with the terminology of the aortic annulus stabilizing device.

Claims 5, 6, and 22 depend upon claim 1 and inherit all problems associated with the claim. For instance, claim 6 requires two end markers on the annulus device, however the specification only supports these particular markers on the outer annulus band.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 5, 6, and 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation "the inner discontinuous aortic annulus stabilizing device" and "the inner continuous sinotubular junction stabilizing device" in lines 9 and 11. There is insufficient antecedent basis for these limitations in the claim.

Claim 1 recites the limitation "the continuous sinotubular junction stabilizing device" in line 7. There is insufficient antecedent basis for this limitation in the claim. Although this feature is introduced in the claim (line 14) it is not until later in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 13, 16, and 23 are rejected under 35 U.S.C. 102(e) as being anticipated by Lansac (US 2005/0065597 A1, cited previously). Lansac discloses a method comprising implanting a discontinuous device (2; fig.2) proximate the aortic annulus (see fig.10, 11) and implanting a continuous STJ device (1; fig.1) proximate the STJ (see fig.10, 11), wherein both are made of synthetic fiber (P0015). The discontinuous device has vertical marks (end surfaces of 2) with an extra margin (sutures 3, 4) of at least 2 mm (inherently must be larger than 2 mm in order to be capable of knotting sutures together). No artificial graft connects the two devices.

Claim 1 is rejected under 35 U.S.C. 102(e) as being anticipated by Chevillon et al. (US 6,511,506 B1, cited previously). Chevillon discloses a discontinuous device (150 and 29) capable of use at an aortic annulus and *capable* of stabilizing the inside and outside of the lumen (inner 150 and outer 29), and a continuous device (31 and 150) *capable* of placement at a sinotubular junction to support the inside and outside (150 inside, 31 outside, 31 which is

continuous). Chevillon discloses both devices (150 or 29 and 150 or 31) to be made of synthetic fiber (col.2, lines 31-34, portions of the discontinuous and continuous device are made of synthetic fiber) and the inner devices to have thinned areas (of 150, the fabric in between struts of 31 is thinner than where the struts 31 are located).

Claims 13 and 15 are rejected under 35 U.S.C. 102(e) as being anticipated by Duran (US 2007/00016290 A1, cited previously). Duran discloses method comprising implanting a discontinuous stabilizing device (suture 17; may be considered discontinuous as it has two free ends tied/knotted together) proximate the aortic annulus and implanting a continuous stabilizing device (suture 18 may be considered continuous as it has one single length used throughout the circumference-instead of a plurality of discontinuous short sutures as used in plicating) proximate the sinotubular junction both being a synthetic fiber (polypropylene suture; P0058). Duran discloses the continuous device (18) to have three markers (20).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 5-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chevillon et al. (US 6,511,506 B2, cited previously). Referring to claim 5, Chevillon discloses placement of markers on the ring devices (col.7, lines 56-59) for positioning purposes, however does not discloses the particular placement claimed (placement of three equally spaced markers). It would have been obvious to one having ordinary skill in the art at the time the invention was

made to place three markers at such a location as such would provide predicable results of increased visual accuracy in positioning.

Referring to claim 6, Chevillon discloses the discontinuous device (29 or 150) having vertical marks (330, 331) at ends thereof with extra margins (350, 351) to allow fixation. Chevillon does not disclose however, what length the marks (330, 331) are from the ends. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the marks about 2 mm from the ends since such would be a mere relocation of parts. *In re Japikse*, 181 F.2d 1019, 86 USPQ 70 (CCPA 1950).

Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lansac (US 2005/0065597 A1, cited previously) in view of Tremulis et al. (US 2003/0069593 A1, cited previously). Lansac discloses the method of treatment substantially as claimed. Lansac discloses a STJ stabilizing device however does not disclose the device to have three spaced markers. Tremulis teaches in the same field of valve repair devices and methods, the use of three spaced markers on repair devices such that the surgeon can identify and orient as desired the device (P0048). It would have been obvious to one having ordinary skill in the art at the time the invention was made combine Lansac's method of repairing a valve region of the heart with a device, with Tremulis's teaching of placing markers on valve devices in order to provide increased identification and orientation during implantation of the device.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHERYL MILLER whose telephone number is (571)272-4755. The examiner can normally be reached on Monday-Friday 7:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached at 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Cheryl Miller/
Examiner, Art Unit 3738

/DAVID ISABELLA/
Supervisory Patent Examiner, Art Unit 3774